EVALUATION OF SUNSCREEN INGREDIENTS, SAFETY, AND POLICIES IN THE UNITED STATES

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ABSTRACT

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Skin cancer is the most common type of cancer in the United States, exceeding incidences of all other cancers combined. The most significant factor in the development of skin cancers is exposure to UV radiations. Therefore, sunscreen has been hailed as a cheap and effective tool to limit UV exposure, thereby preventing skin cancers and other skin diseases. However, in the past decade, some common sunscreen ingredients have been criticized as potential endocrine disruptors, which can cause hormone imbalance and lead to serious health issues. Given the prevalence of skin cancer and sunscreen use in our society, there is much incentive to expand on previous and ongoing scholarship by weighing the efficacy of some sunscreen chemicals in preventing skin diseases given the potential harm of endocrine disruption. The main purpose of the thesis is to understand the existing public view of sunscreen use, and to assess how college students' opinions change or do not change when they are presented with two opposing bodies of evidence surrounding the efficiency and safety of sunscreen. This thesis investigates the debate on the efficacy and safety of sunscreen by 1) understanding the health issues surrounding them, 2) comparing the list of federally-approved sunscreen ingredients in the United States to those of Australia, and 3) using a self-reported survey to understand the sun behavior and awareness among undergraduate students at The University of Texas at Austin. As a conclusion to this study, suggestions regarding the use of sunscreen and future policy actions are recommended.

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Chapter 1: Introduction

Skin cancer is the most common type of cancer in the United States, exceeding incidences of all other cancers combined. According to the American Cancer Society, about 3.3 million Americans suffer from one or more non-melanoma cancers each year, and 76,380 cases of melanoma cancers have been reported in year 2016 alone ("Skin Cancer Facts"). Both non-melanoma and melanoma cancers are almost always curable and are considered lower risk compared to other common forms of cancers, such as lung cancers. However, the yearly incidence of skin cancer is increasing rapidly, and an average of 13,650 patients die from skin cancers each year in the United States (Rogers *et al*., 2015, American Cancer Society). Given its frequency and resulting number of deaths, skin cancer is a significant health concern.

The most significant factor that contributes to the development of skin cancers is exposure to UV radiations. Therefore, sunscreen and its UV-blocking abilities have long been hailed as a cheap and effective tool to limit UV exposure and provide protection from developing skin cancers and other skin diseases. Recent studies suggest that sunscreen can even prevent melanoma—the deadliest form of skin cancer that results in the majority of skin-cancer related deaths—as well (Green *et al*., 2006). Today, the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) both advocate the use of sunscreen in order to reduce the "risks of skin cancer and early skin aging" ("Sun Safety" and "Sunscreen and Sun Protection").

Despite all the health benefits of sunscreen, in the past decade, some common sunscreen ingredients have been criticized as potential endocrine disruptors. Endocrine disruptors are substances that can cause hormone imbalance and lead to serious health issues, such as developmental, reproductive, neurological, and immune defects ("Endocrine Disruptors"). Well-known examples of endocrine disruptors include triclosan and bisphenol A (BPA). Both of these chemicals were once commonly used in commercial products such as pesticides and plastic, but they are now banned in many parts of the world after their negative health consequences to consumers were proven ("FDA Issues Final Rule on Safety and Effectiveness of Antibacterial Soaps," and "France Bans Contested Chemical BPA in Food Packaging"). These examples suggest that the presence of endocrine disruptors in popular products, such as sunscreen, may need more attention. With rising criticism regarding sunscreen, there is much incentive to expand on previous and ongoing scholarship to weigh the efficacy and safety of sunscreen and determine whether sunscreen should continue to be used given its ability to decrease skin cancer and its potential harmful characteristics as an endocrine disruptor.

The purpose of this thesis is to understand the public view of sunscreen and assess any change in their opinion once they are provided with two opposing evidences surrounding the effects of sunscreen use on human health. This thesis will consist of three major parts. First, the debate regarding the efficacy of sunscreen as a UV filter versus its safety concern as an endocrine disruptor is summarized and evaluated using the results of previously-published scientific research. In the second part of the thesis, the effectiveness and speed of regulation process at the federal level are investigated. One of the arguments against the safety of sunscreen is that many of the currently-approved sunscreen chemicals are outdated by more than a decade due to the slow drug investigation and approval processes at the FDA. As a response to this argument, the approved list of sunscreen chemicals in the United States is compared to those in Australia—a country that has the highest incidences of skin cancers in the world—in order to evaluate the efficiency of the current sunscreen regulation system ("Skin Cancer"). Finally, it is difficult to make a generalization regarding whether skin cancer or endocrine disruption are more pressing health concerns. Therefore, in the third portion of the thesis, a self-reported voluntary survey is conducted at The University of Texas at Austin in order to understand students' opinions regarding sunscreen use when they are informed of the debate surrounding sunscreen use. The survey will be used to evaluate students' sun safety measures as well. As a conclusion to this thesis, recommendations for improving sun safety measures and reducing the dangers of contracting skin cancers are discussed.

Chapter 2: Background

Exposure to solar radiation is a health requirement for most living organisms, including humans. For instance, vitamin D is produced in organisms upon their exposure to the sun, in particular to UV-B rays. A lack of vitamin D—due to limited outdoor activities and exposure to the sun—can result in improper mineralization in bones, muscle weaknesses, and other negative health outcomes (Nair *et al*., 2012). However, overexposure to sunlight has also been implicated with multiple health issues, such as skin cancers and sunburn, and avoiding overexposure to the sun has long been advocated using tools such as sunscreen ("UVA & UVB.").

In this chapter, sunscreen and its functions are defined. Furthermore, health concerns associated with exposure to the sun and some sunscreen chemicals are explained before delving into the controversy surrounding the efficiency of sunscreen.

Sunscreen

Sunscreen is a personal care product that is used to shield skin from excessive amounts of sun exposure. Most sunscreen products today consist of multiple sunscreen chemicals, which combine to reduce UV exposure and provide photoprotection. Sunscreen chemicals are categorized based on 1) modes of their function, 2) range of UV radiation that they provide protection from, and 3) degrees of shielding effect from UV radiation.

Sunscreen chemicals can be separated into two main categories of UV blockers and inactive ingredients, based on their functions. UV blockers refer to all chemicals that prevent UV radiation from reaching exposed skin. UV blockers are, in turn, divided into two main categories: physical blockers and chemical absorbers. Physical blockers, or inorganic sunscreens, limit UV exposure by either reflecting or scattering UV rays (Hellwig *et al*., 2012). Most physical blockers are metal oxide nanoparticles, such as titanium dioxide and zinc oxide, coated with inert materials that increase their photostability (Mitchnick *et al*., 1999). They are highly efficient at preventing UV exposure at high enough concentrations and are frequently used in sunscreen products despite giving users a cosmetically unaesthetic opaqueness appearance (Pathak *et al*., 1997).

Chemical absorbers, or organic sunscreen chemicals, reduce the energy of UV radiations in order to minimize their damaging effects on skin. Most chemical absorbers are aromatic compounds with electron-releasing groups that can absorb UV-range radiation. When UV rays are irradiated onto chemical absorbers, chemical absorbers become photochemically excited. Chemical absorbers eventually dissipate energy as a form of less harmful lower energy radiation or heat when they return to ground state (Mancebo *et al*., 2014).

SPF enhancers are a separate category of chemicals that are not active ingredients that increase protection from the sun. They include photostabilizers such as butyloctyl salicylate, antioxidants such as acetyl cysteine, and thickening agents. Inactive ingredients refer to chemicals included in sunscreen products that do not have direct photoprotection abilities. Common categories of inactive ingredients include preservatives such as methylparaben.

Sunscreen chemicals can also be categorized according to the range of UV radiation that they provide protection from. The major types of UV rays that presents health concerns are UV-A and UV-B rays. UV-A rays, which comprise radiation between 320 and 400 nm, amounts for about 95% of UV radiation that come in contact with the Earth's surface. These UV rays penetrate to a deeper layer of the skin called the dermis and have been shown to promote photoaging and non-melanoma cancers. UV-B rays, which comprises radiation between 290 to 320 nm, hits earth's surface more intensely during summer months and during particular times of the day. These UV rays penetrate the epidermis—the outermost layer of skin—and have been shown to result in sunburn and skin cancers. While UV-C rays are the most highly-energetic and damaging, most of them are filtered by the ozone layer and pose less health concerns ("UVA & UVB").

Individual sunscreen chemicals filter out either UV-A rays and are referred to as UV-A screening chemicals or filter out UV-B rays and are called UV-B screening chemicals. Different types of UV rays cause different types of skin diseases, as discussed above. Therefore, most marketed sunscreen products today address the concern for both UV-A and UV-B rays by providing broad-spectrum protection, which is defined by protection from both UV-A and UV-B radiations (Kuritzky *et al*., 2015). Broad-spectrum protection is usually achieved by combining UV-A and UV-B screening chemicals in sunscreen formulations.

Finally, the degree of shielding that each sunscreen product provides as a result of its unique combination of sunscreen chemicals is reflected in terms of Sun Protection Factor (SPF). SPF is the ratio of the amount of UV radiation required before resulting in sunburn to the skin protected by a particular sunscreen chemical or sunscreen product to the amount of UV radiation required for inducing sunburn to unprotected skin. According to the United States Environmental Protection Agency, a sunscreen with SPF 15 blocks about 93% of UV radiation ("Sunscreen: The Burning Facts"). A higher SPF value indicates that the sunscreen protection is more effective and can prevent a greater amount of UV radiation. However, SPF value reflects the degree of protection primarily from UV-B rays, and a higher SPF value does not necessarily mean better protection from contracting skin diseases, such as melanoma (Tachibana).

Skin Cancers

Skin cancer is one of most deleterious skin diseases. It is commonly divided into two main categories: non-melanoma and melanoma cancers. Non-melanoma cancers include all types of skin cancers except melanoma. There are many types of non-melanoma cancers, and basal cell carcinoma and squamous cell carcinoma are the most common types of non-melanoma cancers ("Skin Cancer Facts"). According to the American Cancer Society, non-melanoma cancers account for the greatest incidences among all types of cancer, and basal cell carcinoma accounts for more than 60% of skin cancers (American Cancer Society). These non-melanoma cancers often arise as a result of UV damage to and mutations of skin cells in the epidermis. In particular, squamous cell carcinomas arise as a result of continuous and prolonged sun exposure and are prevalently observed in occupational outdoor workers. On the other hand, basal cell carcinomas arise as a result of intermittent sun exposure and are associated with short-term outdoor leisure activities (“What Is Skin Cancer?"). Non-melanoma cancers are highly treatable upon early discovery. On top of excision surgery and radiation therapy, non-melanoma cancers can be treated using less invasive techniques, such as Mohs micrographic surgery. While non-melanoma cancers are considered less dangerous compared to melanoma cancers and show a higher survival rate, untreated non-melanoma cancers can also metastasize to other organs via lymph nodes, significantly decreasing survival rates.

Malignant melanomas are the rarest but most dangerous form of skin cancer that originate from melanocytes, which are melanin pigment-producing cells that are located in the basilar epidermis. The most common causes of melanoma are mutations and loss of control of major pathways, such as the CDK pathway, that lead to uncontrolled cellular division that characterize cancer (Shane *et al*.). Treatment for melanoma consists largely of excision surgery and radiation therapy to either completely remove or destroy melanoma. These treatment methods are, however, invasive as they target both cancerous cells and healthy cells. Fortunately, the survival rate of early stages of melanoma localized in the site of origin is astonishingly high, 98%, compared to other forms of cancer. However, once melanoma cancers start metastasizing to other organs, especially to the liver, lungs, and bones, the survival rate decreases significantly primarily because it is nearly impossible to determine the origin of metastasized melanoma, thus, treatment becomes extremely difficult. Once melanoma spreads to lymph nodes, the survival rate decreases to 63%, and once melanoma metastasizes to different organs, the survival rate is reduced to 17% (American Cancer Society). Because of its fast rate of metastasis, malignant melanomas account for the majority of deaths due to skin cancer even though they amount to only about 1% of total incidences of skin cancer. Data from the World Health Organization (WHO) informs that the incidence of malignant melanoma has been increasing steadily at an average yearly rate of 4% since the 1980s, reflecting increasing vulnerability to malignant melanoma ("Health Effects of UV Radiation"). In 2011, "The incidence of malignant melanoma is rapidly growing at a faster rate than other forms of cancer" (Melanoma Research Foundation).

Among all forms of cancers, skin cancers have the highest frequency of incidences, but also have the highest survival rates. Therefore, most deaths associated with skin cancers occur as a result of late detection, especially of melanomas. Delay in the detection and treatment of any form of skin cancer substantially increases the possibility of metastasis to different organs and difficulty in identifying the original site of cancer. In fact, many government agencies, such as the Center for Disease Control (CDC), acknowledge the difficulty of detecting skin cancers due to their physical resemblance to moles. Furthermore, individuals with darker skin experience a higher mortality rate even though skin cancers occur at higher frequencies in those with lighter skin. This seemingly-contradicting evidence has been explained by lack of skin health awareness and a common but false perception that darker skin provides full coverage against the harmful effects of UV radiation. Such false sense of security factors into late detection of skin cancer and lowers survival rates among those with dark-colored skin (Bradford).

Sunburn

Sunburn, or UV erythema, is redness of skin due to prolonged exposure to the sun, particularly to UV radiation. It is primarily caused by a type of UV radiation called UV-B ray. The incidence of sunburn is quite high; according to CDC, 50.1% of adults surveyed in 2010 claimed to have experienced at least one sunburn in the past 12-month period. This value shows little reduction from the incidence of sunburn in 2000 at 50.9%. Furthermore, while the Caucasian population experiences the highest rate of sunburn at about 65%, populations with darker skin also experienced sunburn, as indicated by 13% for African Americans and 33% for

Hispanic populations. The rate of sunburn also did not vary from 2000 and 2010 across races ("What Is Skin Cancer?").

While sunburn does not result in immediate serious symptoms, its occurrence and frequency may serve as an indicator for more malignant skin diseases. For instance, sunburn has been shown to increase risks of melanoma, especially among the young ("What Is Skin Cancer?"). 43% of child melanoma survivors from the California Cancer Registry were sunburned in the past year, indicating that sunburn is correlated with melanoma, at least for younger populations (Dennis *et al*., 2008).

Endocrine Disruption

The endocrine system coordinates and regulates multiple important functions within the body, including metabolism, neuronal and physiological growth and development, and reproduction. Endocrine disruption is defined as interruption of the body's innate endocrine system by endocrine disruptors. Endocrine disruptors often resemble the chemical structure of naturally-occurring hormones, and they misleadingly signal hormone receptors. As the endocrine system regulates many of the bodily processes and growth, endocrine disruptors can compromise the overall health of and development of the organism. Furthermore, studies on endocrine disruption have shown devastating health consequences of disturbances to physiological and neurological development, reproductive health, and the immune system, especially to developing fetuses ("Endocrine Disruptors").

Many endocrine disruptors have been identified and banned due to their harmful effects. The popularity of a chemical in commercial products does not automatically correlate to its safety. Some of the most widely used additives were found to cause endocrine disruption and have been banned. One example of such an endocrine disruptor is triclosan. Triclosan is a popular antimicrobial agent that has been widely used in a broad range of consumer products, including antibacterial soaps, school supplies, clothes, and toothpastes. However, various human and animal studies have shown the negative health consequences of exposure to triclosan, especially for developing fetuses. One study showed that the concentration of triclosan in pregnant women's urine samples was negatively correlated with the growth of the fetus in the late gestation of pregnancy and with head circumference upon birth (Philippat *et al*., 2014). It has also been shown to disrupt the placenta in pregnant rats by decreasing naturally occurring hormones, such as progesterone and estradiol in serum while up-regulating receptors of these naturally-occurring hormones (Feng *et al*., 2016). In one study of rats, prolonged exposure to triclosan during pregnancy significantly reduced the birth and survival index of offspring, and affected rates of thyroid homeostasis of the mothers (Rodriguez *et al*., 2010). Another recent study showed that even short-term exposure to triclosan during pregnancy can alter patterns of gene expression and lead to impairments in fetal hypothalamic transcriptomics that result in "disturbances of the food intake and energy homeostasis, the thyroid hormone system, and the reproductive function, with possible consequences in the pattern of growth" (Rabaglino *et al*., 2016). Triclosan was officially banned by the FDA in 2016, and it can no longer be used in antibacterial soaps and other commercial products in the United States ("FDA Issues Final Rule on Safety and Effectiveness of Antibacterial Soaps").

Another popular chemical that was recently controversial for its endocrine disrupting effects is Bisphenol-A (BPA). BPA is a common ingredient in plasticware. Previous research has shown that when pregnant mothers come into contact with BPA, the chemical can negatively impact fetal growth, and it is also excreted through breast milk (Padmanabhan *et al*., 2008, Sun *et al*., 2004). Animal studies also have shown that exposure to BPA can cause problems in heart functions, such as arrhythmia (Yan *et al*., 2011, Posnack *et al*., 2014). Currently, the FDA has not taken any legal action to ban BPA, as it claims that BPA is "safe at the current levels occurring in foods" ("Bisphenol A (BPA): Use in Food Contact Application"). However, in 2009, six of the largest producers of baby bottles have ceased to include BPA in their formulations ("No BPA for Baby Bottles in U.S."). Several additional companies have also voluntarily removed BPA from the formulations of their products as public criticism of BPA rose since then.

Just as with triclosan and BPA, many chemicals have been shown to be potential endocrine disruptors with adverse health consequences. For instance, a common preservative called butylparaben was shown to be an endocrine disruptor for which exposure during the third trimester of pregnancy is correlated with adverse birth outcomes in newborns, such as lower birth weight (Bienkowski). As shown above, hormonal interruption and alterations due to endocrine disruptions can negatively influence fetal physical development, as reflected by suboptimal birth outcomes in newborns.

Furthermore, endocrine disruptors can have negative influences on the cognitive development of young children. Prenatal exposure to an endocrine disruptor called polychlorinated biphenyls (PCB) has been negatively associated with IQ and other cognitive functions in children (Eubig *et al*., 2010). Children with high urinary BPA or organophosphate pesticide concentrations indicate attention deficit problems. Children with high urinary BPA concentrations exhibit higher emotional reactivities (Roen *et al*., 2015). These studies indicate that endocrine disruptors are common environmental factors in the lives of not only pregnant women but also young children. Also, they indicate that young children are susceptible to neurodevelopmental problems as a result of their exposure to various endocrine disruptors that are common environmental chemicals. There is little known about the reversibility of or treatment for health issues caused by endocrine disruptors.

Skin Allergy

Skin allergy is identified by symptoms of irritation, itching, swelling, and redness of skin (CDC). It is developed by sensitization then subsequent exposure to an allergen that results in immune reactions to the allergen chemical. The skin allergy that is caused by chemical or allergens, such as sunscreen chemicals, is referred to as contact dermatitis. Photoallergic contact dermatitis is a form of contact dermatitis that displays skin allergy symptoms upon exposure to sunlight. Once a skin allergy has developed, symptoms can be suppressed by steroids and other medications.

Chapter 3: UV Filters in Sunscreen and Current Arguments

In the past decade, there has been a heated debate regarding the safety of sunscreen chemicals that are marketed in the United States. Sunscreen limits UV radiations and prevents many of the sun-derived skin diseases of concern. Especially in Texas, where residents are exposed to a greater length and degree of UV rays due to its geographical location close to the equator, the effects of sunscreen are highly desirable. Recently, however, some of these sunscreen chemicals have been recognized as potential causes of endocrine disruption and skin allergies (Kim *et al*., 2014). The emerging data that warns of the potential danger of endocrine disruptors cannot be overlooked because endocrine disruption affects both the development of the fetus and children and the reproductive health of adults. Given that children and pregnant women are encouraged to apply sunscreen, sometimes more often so than for adults, the negative health consequences that sunscreen may pose to these vulnerable populations cannot be ignored. Therefore, it is important to examine both sides of the argument and analyze them carefully.

Arguments for the Use of UV Filters

The preventive effects of sunscreen are clear and have been proven over the course of many decades since the 1940s when sunscreens were first produced ("Sunscreen: A History"). Today, the Centers for Disease Control and Prevention (CDC) recommends the use of sunscreen with an SPF of 15 or higher along with long-sleeved clothing, hats, and sunglasses as an effective method of personal protection against damaging UV rays ("Sun Safety").

The primary purpose of sunscreen is to either reduce or prevent excess skin exposure to UV radiations, and the protection that sunscreen application provides against sunburn is wellestablished and substantial. The use of sunscreen reduced the number of children who were sunburnt by 60% according to one study, even though there is evidence that additional factors, such as age and frequency of sunscreen re-application, can reduce the effectiveness of UV protection (O'Riordan *et al*., 2003). One study tested sunscreen with an SPF 15 and above, and SPF 15 was shown to be sufficient to prevent sunburn under a strong summer sun, but variations in the thickness of the applied sunscreen resulted in different levels of protection from sunburn (Pissavini *et al*., 2013). Another study tested the efficacy of sunscreen in preventing sunburn. It found that at an earlier age, the participants experienced less severe sunburn even though they did not regularly apply sunscreen on themselves; however, at an older age, the same participants experienced more severe sunburn incidences with the use of sunscreen (Ghiasvand *et al*., 2015). Even though the protection against UV radiation and sunburn seems to vary depending on the modes of sunscreen application, prevailing data indicates that sunscreen use is effective in protecting human skin against sunburn due to overexposure under the sun.

On top of preventing sunburn, continuous use of sunscreen can also prevent skin diseases, such as actinic keratosis. Actinic keratosis refers to scaly growth of the skin due to sustained sun damage ("What Is Actinic Keratosis"). According to the Mayo Clinic, a small proportion of the people who suffer from actinic keratosis can also develop skin cancer (Mayo Clinic Staff). A recent study performed in Japan indicates that the long-term use of sunscreen can also prevent the development of actinic keratosis and the progression of actinic keratosis to squamous cell carcinoma in aged patients (Kunimoto *et al*., 2016).

The use of sunscreen has also been proven to prevent the development of non-melanoma cancers. Basal cell carcinoma develops mostly on sun-damaged areas of the skin. The use of sunscreen has been shown to reduce the incidences of by 25% in a previous randomized study (van der Pols *et al*., 2006). One study estimated that the regular use of sunscreen prevented about 9.3% of Australians, or 14,192 people, from developing cutaneous squamous cell carcinoma—a form for non-melanoma cancer—in 2008 (Olsen *et al*., 2015).

The effect of sunscreen on preventing melanoma had been unknown for many years. Recently, however, the preventive effect of sunscreen on reducing melanoma cancers—the most dangerous form of skin cancers—has also been reported in many scientific studies. One study indicated that the use of sunscreen with an SPF of greater than 15 can reduce melanoma incidence among all women between ages of 40 and 75 by 18% (Ghiasvand *et al*., 2015). Another study indicated that incidences of melanomas were reduced by 50% among a group of participants that were assigned sunscreen (Green *et al*., 2010).

Skin diseases have been a topic of serious health concern recently, especially with the sheer number of the population that suffers from sunburn and skin cancers. As the pathology of skin cancers are better understood now, there is an emphasis on preventing relatively minor skin diseases, such as sunburn and actinic keratosis, which have been proven to positively correlate with instances of skin cancer development. The ongoing research on skin diseases has often been paired with the test of the preventive effect of sunscreen to reduce the likelihood of attaining these skin diseases. As the evidences above indicate, there seems to be a substantial and growing body of evidences that attest to the benefits of sunscreen in preventing these skin diseases via limiting overexposure to UV rays.

Arguments against the Use of UV Filters

Sunscreen effectively prevents overexposure to UV radiations, thereby preventing skin cancers and sunburn. However, the use of sunscreen has raised new health concerns: some of the most widely-used sunscreen chemicals are endocrine disruptors and skin irritants and allergens.

Sunscreen chemicals have been debated for their endocrine disrupting abilities. One recent study indicated that based on an endocrine receptor binding activity prediction model, of 32 common sunscreen ingredients, seven of them—benzophenone-4, benzophenone-5, 4-methylbenzylidene camphor, benzophenone-1, benzophenone-2, and bezophenone-7—were identified to be active estrogenic compounds (Hong *et al*., 2016). All of these studies seem to indicate that sunscreen chemicals can influence the living system and potentially disrupt hormone balance, leading to further negative health effects.

One study tested for the effect that benzophenone-2 can have on the development of embryos using a zebrafish model (Fong *et al*., 2016). Fong found that 40 μM concentration of the chemical resulted in lipid accumulation within five days. Unusual lipid regulations caused facial malformation and suppressed the normal development of cranial neural crest cells. These data indicate that on top of exhibiting characteristics of endocrine disruptors, some sunscreen ingredients can result in the adverse consequences that endocrine disruptors have, such as a negative influence on embryo development.

Even though physical UV blockers are considered as the more stable ingredient of sunscreen, some physical blockers seem to also influence the human immune and reproductive system adversely. For instance, titanium dioxide is a common physical blocker used in sunscreen products. However, some evidences indicate that the presence of titanium nanoparticles resulted in a significant reduction of the inflammatory cell infiltration and apoptosis in mouse models (Hong *et al*., 2016). Furthermore, the exposure to titanium dioxide nanoparticle also has been shown to reduce the reproductive fertility of a mouse model due to decreased spermatogenesis, testicular damage, and alterations to testis-specific gene expression that occur when titanium dioxide crosses the blood-testis barrier and accumulates in the testis (Hong *et al*., 2016).

Furthermore, accumulating scientific evidences indicate that the presence of a common physical blocker titanium dioxide can result in co-exposure to other endocrine disrupting chemicals in certain human organs. Fong showed that titanium dioxide nanoparticles can function as a carrier of common endocrine disruptors such as BPA. As titanium oxide nanoparticle can access to and accumulate in the liver, brain, and gonad tissues, the bioavailability and the effect that endocrine disrupting chemicals are significantly enhanced. As a result, reduction in the level of naturally-occurring hormones, such as estranol and follicle-stimulating hormones, were reduced (Fong *et al*., 2016).

Another health concern of some sunscreen chemicals is skin irritations and skin allergies. Previous research indicates that two common UV blocking chemicals—benzophenone and dibenzoylmethanes—cause allergic and photoallergic reactions. Benzophenone-3 is responsible for 70% of sunscreen allergies. Inactive ingredients in sunscreen, such as methylisothiazolinone, also induce allergic reactions.

Even though the amount of the potential endocrine disrupting sunscreen chemicals may be used in small concentrations in sunscreen products, some tend to accumulate in the human body. This poses a potentially serious health concern because the damage induced by certain topically-applied sunscreen chemicals may have as much health consequences as other controversial endocrine disruptors that are ingested. One study indicates that alpha-tocopherol acetate has been shown to be absorbed in the skin and plasma and has also been suggested to enhance skin cancer development in a mouse carcinogenesis model (Alberts *et al*., 1996). Previous studies have shown that some active ingredients, such as benzophenone-3, have been shown to be absorbed in the skin (Krause *et al*., 2012). Another study analyzed the amount of UV filter chemicals and paraben from placentas that were collected after delivery, and benzophenone-1, methyl paraben, butyl paraben, and benzyl paraben were identified in the placenta sample (Valle-Sistac *et al*.). There are further scientific evidences of detecting benzophenone-3 and other endocrine disruptors found in personal care products in the urine samples of Danish children, as well as in the breast milk of mothers (Frederiksen *et al*., 2016 Krause *et al*., 2012).

The evidences against sunscreen use due to potential endocrine disruption has accumulated since the argument arose a decade ago. Existing evidences suggest that on top of displaying the common characteristics of the mobility and biodegradation properties of known endocrine disruptors, common UV filter chemicals also seem to display effects in disrupting the reproductive and immune health of the subjects and model animals.

Discussion

Previous scientific studies that discuss the health implications of sunscreen ingredients were evaluated in this section of the thesis. The evidence that proves the benefits of sunscreen is substantial, but the arguments against the use of sunscreen may also warrant more attention. As sunscreen is not only widely used but also is advocated by many governmental agencies such as the CDC, it is important to examine the health concerns related to the use of these sunscreen chemicals. Especially, the consequences of endocrine disruptors are potentially grave, especially for the populations of pregnant women and young children, making the discussion of potential dangers of sunscreen very pertinent.

To begin with, the benefits of sunscreen in protecting skin and reducing instances of radiation-induced skin diseases were clear from previous studies. The application of sunscreen has shown clinical successes, especially in long-term studies that analyzed the correlation between sunscreen use and non-melanoma cancers over periods of more than 10 years. The reduction in the instances of skin diseases seem to indicate that sunscreens are indeed very successful at limiting damaging UV radiations from reaching the skin.

The cost of sunscreen is quite minimal given all of the health-related benefits of sunscreen. In 2010, the procedures to remove melanoma cancers could cost between $565 and $3,680 depending on the stage that it is found (Guy *et al*., 2012). Even if one can afford to pay for the expensive procedures to remove melanoma cancers, the chances of survival decrease dramatically depending on when the melanoma was identified. Given the cost and risks associated with the development of skin cancers, effective prevention of skin cancers using sunscreen application is extremely cost-effective.

One limitation in most of the studies that investigated the potency of sunscreen in disease prevention is that when sunscreen products were tested, none to a small number of research studies done on the efficacy of sunscreen listed the specific brands or concoctions of sunscreen ingredients that were put to test. Therefore, while these studies prove the effectiveness of sunscreen in general, they do not provide further details about how each specific sunscreen ingredient correlates with the clinical successes that they observed. Even if they were to disclose the identities of the ingredients, the existing results would not be very resourceful in identifying the health benefits of individual sunscreen chemicals.

This poses a challenge for the purpose of this thesis. The benefits of individual sunscreen chemicals cannot be correlated directly to their potential endocrine disrupting effects. While there are existing data on the modes and level of protection provided by each sunscreen chemical, they do not detail long-term health benefits, such as prevention of non-melanoma and melanoma cancers, and they cannot be used to compare evidences of potential endocrine disruptions against particular sunscreen ingredients.

The data suggesting potential endocrine disruption caused by sunscreen seem to accumulate over the years as well. In particular, different types of benzophenones seem to pose greater health threats than other sunscreen chemicals that were studied, with their abilities to penetrate skin and interact with endocrine receptors. Furthermore, data seem to suggest that even though most sunscreens are topically-applied, and not ingested, they may have greater influences on health than previously thought.

Some scientists have used mathematical models to calculate the amount of controversial sunscreen ingredients, such as oxybenzone needed to cause harm on human health. They concluded that 277 years of daily application of sunscreen is necessary to demonstrate high estrogenic and antiandrogenic activities of oxybenzone (Janjua *et al*., 2004). However, oxybenzone is present in many commercial products, such as plastics, hair sprays, and nail polishes. Therefore, the claim that daily exposure to oxybenzone is not low enough to be negligible may not necessarily be true.

Previously, physical blockers were considered to be more stable than chemical filters and are, therefore, a safer type of sunscreen chemical. However, recent evidences suggest that titanium dioxide nanoparticles, a common physical blocker, may have negative influences on health by 1) accumulating in gonad tissues and 2) acting as a carrier molecule and delivering other endocrine disruptors to specific organs or tissues in the body. Given its newly-discovered characteristics, titanium dioxide and other physical blockers need to be researched further regarding their safety as individual chemicals as well as their safety when combined with other endocrine disrupting chemicals.

Another concern that is not addressed in most articles is that sunscreen is a combination of a wide range of ingredients. It not only includes a category of chemicals that are considered UV blockers, but it also includes photostabilizers and inactive ingredients. Most of the focus of the discussion has been placed on UV blockers, which contributes to the majority of the UV protections by reflecting or dissipating UV rays. However, some categories of non-UV blockers, such as photostabilizers, increase the SPF value by stabilizing the typical UV blockers. These chemicals do not have to be approved by the FDA with the same strict guidelines that UV blockers are examined. While most of the inactive ingredients are used popularly in cosmetic products and have been proven safe, their safety was not necessarily examined when they are combined with UV blockers. As discussed above, titanium dioxide nanoparticles are an example of how the study of the interaction between multiple chemicals can benefit a more holistic understanding of the health concerns that endocrine disruptors pose. The titanium dioxide intensifies the effect that endocrine disruptors become available to human organs. There has not yet been comprehensive research regarding the effect that different combinations of sunscreen ingredients have on health at different doses, and such data is necessary in order to develop a safer alternative to existing sunscreen while retaining the current health benefits that sunscreen has on limiting UV exposure on skin.

While it has been proven over the years that sunscreens are very potent for prevention of UV exposure, the emerging data regarding specific sunscreen ingredients suggest that the endocrine disruption resulted by certain sunscreen chemicals—especially benzophenones—cannot be ignored. At the same time, the scientific evidence supporting each side of the controversy may not be contending on the same level. Previous research that advocates the use of sunscreen tends to focus on the therapeutic effects of sunscreen products—which are a combination of sunscreen ingredients—whereas much of the previous research that discredits sunscreen seems to focus on the endocrine disrupting effects of individual sunscreen ingredients.

The reasonable solution to the controversy surrounding sunscreen very much seems to be the continuing use of more stable sunscreen ingredients, such as zinc oxides, and substituting more controversial ingredients such as benzophenones with safer alternatives.

Chapter 4: Comparison of United States Sunscreen Regulation to Counterparts in Australia

Currently, sunscreens are considered as a drug in the United States, requiring high standards for approving new sunscreen chemicals. However, due to such high standards, no new sunscreen chemical has been approved since the early 2000s, and there has not been another alternative sunscreen ingredient that was approved to replace the currently-debated ones on the market.

Over the years, the critics of existing sunscreen have complained of the “slow” approval processes of the FDA that seems to compromise the efficiency and safety of sunscreen by not allowing newer sunscreen chemicals to be circulated in the market. Therefore, this comparison between the U.S. and Australian approved list of sunscreen chemicals addresses the weakness of U.S. policies and potential policy alternatives.

Sunscreen Regulation and Currently Approved Sunscreen Chemicals

In the United States, all sunscreen chemicals have to be approved by the Food and Drug Administration (FDA) before they can be marketed to the public. Sunscreen is considered as a form of drug according to the FDA, subjecting new sunscreen chemicals to a greater level of scrutiny during their approval processes compared to other personal care items that are categorized as cosmetics.

In the past decade, no new sunscreen chemicals was approved due to strict approval process that is required of drugs in the United States. The Sunscreen Innovation Act (SIA) was passed in order to expedite the approval process for the ingredients that are currently used widely in the countries of the European Nations, such as amiloxate, bemotrizinol, and bisoctrizole ("Sunscreen Innovation Act (SIA)"). However, even such efforts did not result in the approval of additional sunscreen chemicals, as the FDA decided that the proof of their safety is not substantial enough. A lack of newly approved sunscreen despite legislative efforts, such as SIA, reflects the high standards of safety that the FDA attempts to ensure in the American sunscreen market.

In order to understand whether the criticism against the FDA's regulation processes are valid, the approved list of sunscreen ingredients in the United States was compared to that in Australia. Australia was chosen for the purpose of this thesis because it has one of the world's highest incidences of sunburn, non-melanoma cancers, and melanoma cancers (Australian Institute of Health and Welfare, AAoCR). A large number of skin-related diseases that arise among the citizens and residents of Australia has caused both the Australian government and public to be much invested in skin cancer research and distributing sun safety measures.

Sunscreen chemicals are regulated by the Therapeutic Goods Administration (TGA) under the Department of Health in Australia. The Therapeutic Goods Administration currently has four categories of sunscreens—listable, registrable, exempt, and cosmetic. Under this system, some sunscreen qualities can be included in cosmetic products, such as foundation, without specifying SPF values. However, all sunscreen that label its product with SPF values fulfill the definition of therapeutic sunscreen and are regulated as drugs. The TGA's categorization of most forms of sunscreen as drugs makes Australian sunscreen regulation to be a more reliable comparison to the American one, compared to other countries that consider sunscreen as a cosmetics.

In order to understand whether the existing sunscreen active ingredients in United States are outdated as claimed by critics, the lists of approved sunscreen chemicals in Australia and the United States are compared. Currently, 16 approved sunscreen ingredients can be used in the United States ("Code of Federal Regulations Title 21", Figure 1). Among the 16 chemicals, three are UV-A filters, nine are UV-B filters, two are both UV-A and UV-B filters, and two are physical blockers.

In comparison, 30 sunscreen ingredients are currently approved for use by TGA in Australia ("Permitted Ingredients," Figure 2). Among the 30 ingredients, ten are UV-A filters, thirteen are UV-B filters, five are both UV-A and UV-B filters, and two are physical blockers. In particular, 16 of the approved sunscreen chemicals in Australia matches that of the United States. However, maximum dosage of the approved ingredients differs for some. Aminobenzoic acid (PABA) is approved for use at a higher amount in the United States than in Australia by 5%. Avobenzone, cinoxate, octyl methoxycinnamate, oxybenzone, and zinc oxide are approved for use at a higher amount in Australia than in the United States (Figure 1). The remaining 14 sunscreen chemicals that are approved by TGA are currently not approved for use in the United States. These 14 sunscreen chemicals are approved to be used in higher maximum concentrations than most of the FDA approved sunscreen ingredients.

Names of Ingredients	FDA Approved Amounts (%)	TGA Approved Amounts (%)
Aminobenzoic Acid (PABA)	< 15 %	< 10 %
Avobenzone	< 3 %	< 5 %
Cinoxate	< 3 %	< 6 %
Dioxybenzone	< 3 %	< 3 %
Homosalate	< 15 %	< 15 %
Methyl Anthranilate	< 5 %	< 5 %
Octocrylene	< 10 %	< 10 %
OctylMethoxycinnamate	< 7.5 %	< 10 %
Octyl Salicylate	< 5 %	< 5 %
Oxybenzone	< 6 %	< 10 %
Padimate O	< 8 %	< 8 %
Phenylbenzimidazole Sulfonic Acid	< 4 %	< 4 %
Sulisobenzone	< 10 %	< 10 %
Titanium dioxide	< 25 %	< 25 %
Trolamine Salicylate	< 12 %	< 12 %
Zinc Oxide	< 25 %	No Limit

Figure 1: Comparison List of Approved Active Sunscreen Ingredients in the United States (FDA) and in Australia (TGA). The ingredients that are approved with higher maximum concentrations are highlighted.

Names of Ingredients	TGA Approved Amounts (%)
Amiloxate	< 10 %
Benzophenone-5	< 10 %
Bisimidazylate	< 10 %
Diethylamino-hydroxybenzoyl-hexylbenzoate	< 10 %
Ecamsule	< 10 %
4-Methylbenzylidene Camphor	< 4 %
Meroxyl SL	< 6 %
Meroxyl SO	< 6 %
Mexoryl XL	< 15 %
OctylTriazone	< 5 %
Polysilicone-15	< 10 %
Tinosorb A2B	< 10 %
Tinosorb M	< 10 %
Tinosorb S	< 10 %

Figure 2: List of TGA-Approved Active Sunscreen Ingredients. These ingredients have not been approved by the FDA.

Discussion

The U.S. federal government's approach to chemicals management sets a very high bar for the proof of harm that must be demonstrated before regulatory action is taken. Such efforts are admirable and true to the spirit of Frances Oldham Kelsey. With rigorous approval processes, the FDA attempts to eliminate potentially harmful chemical ingredients from entering the market.

However, the FDA's approval process has a disadvantage. Because sunscreens are considered as drugs according to the FDA, the approval of each sunscreen chemical has been extremely slow and difficult as they need a substantial amount of proof to demonstrate their effectiveness. Due to slow the approval and alteration policies that the FDA endorses, it is not possible to determine whether its policies are outdated or not comprehensive enough unless they are compared with those of other nations. Because Australia invests much effort in developing and confirming new measures to reduce the occurrence of skin diseases, the legal schema of Australia surrounding sunscreen ingredient approval and regulations were considered.

Currently, the Australian Therapeutic Goods Administration maintains two different categories of sunscreen regulations: primary and secondary sunscreen (National Coordinating Committee on Therapeutic Goods). Under this system, any products that are labelled SPF are regulated as primary sunscreen, which are considered and are regulated as drugs. The list of primary sunscreen chemicals is larger than that of the United States, but it also includes all of the sunscreen ingredients that are currently approved in the United States. This indicates that the critics' concern regarding the slow sunscreen approval processes of the FDA is reasonable from the smaller number of acceptable sunscreen ingredients.

The critics have also argued that the list of approved sunscreen chemicals compromise the sun safety of the public because they are obsolete and do not provide either safe or effective protection. Because the same sunscreen ingredients that are approved in the United States are approved and are used in Australia, sometimes at a higher maximum dosage, the second argument may not necessarily be true. However, the number of UV-A ingredients approved by the United States is much smaller compared to the number of UV-A chemicals available in Australia. This is concerning especially because emerging body of data indicates that both UV-A and UV-B contribute to skin diseases, especially skin cancers, and broad-spectrum sunscreen are favored over traditional sunscreens that emphasize only UV-B protection.

The unique Australian system of maintaining two categories of sunscreen offers a potential solution that satisfies both the proponents and critics of the existing sunscreen regulation policies in the United States. A potential sunscreen proposal would involve the adoption of a new sunscreen category that is considered as non-drug, just as with sunscreen policies in Australia. With this system, it will be possible to allow some newer sunscreen products that have already been approved and are in use in foreign countries such as the European Nations in cosmetics and other personal care products so that a wider variety of ingredients can enter the market for consumers to choose. These newer types of sunscreen ingredients would still be under FDA regulation for their safety, but they would not be scrutinized or have to undergo as extensive approval and regulation processes that current sunscreen policies require.

In conclusion, this comparison study that investigates the legal framework of sunscreen regulation in Australia and the United States indicated that the existing structure of FDA approval and regulation policies on chemicals that are considered as a drug—in particular sunscreen for the purpose of this thesis—is quite valid in terms of its safety. Even though some critics pointed out that the rate at which sunscreen chemicals are approved is slow and cause the existing sunscreen chemicals to be outdated, the safety of the approved list of sunscreen seems to be quite reliable. However, the much smaller list of FDA-approved sunscreen ingredients does indicate that the speed at which newer sunscreen chemicals is approved is slow. However, by resolving the rigidity of the FDA's new sunscreen ingredient approving processes slightly through the introduction of a new category of sunscreen, it would be possible to make a greater number of sunscreen ingredients available to the public while continuing to maintain a level of safety and efficiency regulation.

Chapter 5: Case Study - Self-Reported Survey

In the previous sections of the thesis, the controversy surrounding sunscreen use was evaluated in terms of literature and policy review. However, these methods of analysis reflect limited information regarding both the extent of the public's knowledge about the health consequences surrounding sunscreen use and public opinion change as a result of considering the potential negative effects of sunscreen. While some previous studies evaluated participants' sun behaviors and explored participants' opinions regarding sunscreen, these questionnaires did not consider a change in the participants' decisions to either use or limit their sunscreen consumption. They also did not specifically measure the behaviors and opinions of young adults—in particular those who are current undergraduate students. Therefore, a self-reported, voluntary survey was conducted as a part of this thesis in order to better understand the sun protection behaviors and knowledge about sunscreen among undergraduate students (sample size = 72) at The University of Texas at Austin. The three main purposes of this survey are to 1) understand the common behaviors and knowledge participants hold regarding sun safety and the use of sunscreen, 2) measure the proportion of the students who were informed about endocrine disruption and certain sunscreen chemicals as endocrine disruptors, and 3) identify any opinion change that arises when they are informed about the positive and negative influences of sunscreen chemicals. The results of the survey are used as an important indicator of the direction and extent of change in student opinions and a major consideration for the determination of the perceived efficiency versus danger of sunscreen based on the existing evidence surrounding the controversy.

Methodology

This survey was performed as a case study to evaluate sun safety knowledge and behaviors of undergraduate students at The University of Texas at Austin. For this case study, 72 undergraduate students who are 18 years old or older and are currently enrolled at The University of Texas at Austin were asked to complete the survey. Because the target population was students at The University of Texas at Austin, all survey advertisements were communicated on campus. In order to request students to complete this survey, professors who were teaching courses in the Fall 2016 semester were contacted for an opportunity to talk to and ask students to fill out the voluntary survey.

The survey was titled identically as the title of the thesis, "The Evaluation of Sunscreen Ingredients, Safety, and Policies in the United States," and its study number is 2016-09-0063. The purpose and the content of the survey were reviewed and approved by the Institutional Review Board (IRB) at The University of Texas at Austin on November 22, 2016. The survey results were collected between November 21 and December 1, 2016.

The survey form was posted on Qualtrics, where participants answered the survey questions. The participants accessed the survey via the anonymous link and QR codes provided, and they answered the survey questions on their digital devices. The method of survey distribution ensured that individual participants could not be identified. The survey results were collected and securely stored on Qualtrics, and all survey results will be securely stored on Qualtrics until the last day of December 2016. In order to maximize confidentiality and privacy, the survey also did not ask participants to record personal identifying information.

The survey was completed voluntarily, without any monetary rewards. The written cover letter at the beginning of the survey described the general purpose of the survey and obtained consent from all participants. The survey was designed so that the participants could choose to answer or skip questions when completing the survey. No to minimal risk to participants was expected from the topics and questions included in the survey.

The survey included 28 questions and consisted of four sections. In the first section, general demographic data was collected in order to identify the skin type of the participants based on some questions from the Fitzpatrick Skin Typing Test (Fitzpatrick). In the second section, more specific questions regarding the participant's sun behavior and their opinions on sunscreen and skin cancers were asked. In the third section of the survey, the participants were provided an intervention consisting of a brief bullet-pointed list of the pros and cons of using sunscreen (Figure 3). In the last portion of the survey, any change in participants' opinions regarding their sun behaviors, sunscreen use, skin cancers, and endocrine disruptions were analyzed by purposefully duplicating some of the questions that were asked in the second section of the survey. Most survey questions were adapted from previously published research regarding sun safety, and several questions were modified slightly to fit the purpose of this survey (Agbai et al., Fitzpatrick, Glanz et al., "Is sunscreen safe?", Krause et al.).

Once the survey data collection was completed, the results were analyzed using statistical tools. Statistical software named R and the built-in statistical analysis tool on Qualtrics were used as the two main methods of analysis. The data was evaluated to first understand the general demographic information about the sample in terms of their gender, skin sensitivity, and any family history of skin cancer. Then, the participants' opinions regarding their sun behaviors and sunscreen use were determined by examining their responses on the average amount of time spent outdoors, frequency of sunscreen use, and their awareness and preference for any individual sunscreen chemical. Any change in participants' opinions regarding sunscreen use was measured due to intervention was determined by statistically analyzing any statistically significant shift on the perceived efficiency, safety, and purpose of sunscreen use. Any change in the perceived effects of skin cancer and endocrine disruption and their perceptibility were measured as well. Finally, the seriousness of sunscreen use on health and the effect of endocrine disruptors on health was evaluated.

Results

Seventy-two undergraduate students at The University of Texas at Austin provided consent and completed the entire survey, and only the data from these participants were evaluated for the purpose of this thesis. The survey data of the participants who did not give consent or did not complete the survey through the end was not considered.

First, the general demographic data and sun behavior of participants were considered. Twenty-nine participants (40.28%) identified themselves as males, and 43 (61.18%) participants identified themselves as females. Twelve participants answered that they have a family history of skin cancer (16.67%), and 60 students answered that they do not have a family history of skin cancer (83.33%). Questions 2 and 3 were adopted from the Fitzpatrick Skin Typing Test in order to determine the distribution of the skin types of the participants (Fitzpatrick). Traditionally, the test consists of a series of questions that assign scores to each skin type then it uses the summation of the scores in order to determine the skin type of the subject on a scale of Type I to Type VI. In order to minimize the length of the survey, the description of each skin type were offered as the answer choices that students could choose, instead of asking a series of questions to identify an accurate skin type. Six participants described their skin type as “always burn, blister, and peel” which corresponds to skin type I (8.33%), and 5 participants reported that their skin “often burns, blisters, and peels” which corresponds to skin type II (6.94%). Twenty-three participants answered that their skin “sometimes burns” which corresponds to skin type III (31.94%), 26 participants reported that their skin “rarely burns” which corresponds to skin type IV (36.11%), and 12 participants responded that their skin “never burns” which corresponds to skin type V and VI (16.67%).

The amount of hours that students spent outdoors during a weekday and on a weekend day was collected as well. Participants spent a median of 1 to 2 hours outdoors during a regular weekday and a weekend day. There was no significant difference between the average time that participants spent outdoors between a weekday and on a weekend day with a p-value of less than with 95% confidence. When asked about sunscreen use, 43.06% of the students answered that they apply sunscreen only when they expected to be outdoors, 8.33% of the participants reported that they apply sunscreen when they are expected to be indoors or outdoors, and 48.61% responded that they sometimes apply sunscreen when they are expected to be either indoors or outdoors.

Second, general opinions and behaviors that the participants may hold regarding any particular sunscreen chemical were identified. When students were asked whether they read ingredient labels, 15.28% of the participants answered “yes” and 84.72% answered “no.” They reported that they identified acrylates, avobenzone, paraben, titanium, titanium dioxide, and zinc oxide. When they were asked if they avoid any particular ingredient, 2.78% of the participants reported that they avoid sunscreen products with palm oil, paraben, and chemical sunscreen, and 95.83% responded that they do not. Furthermore, when participants were inquired if they prefer the inclusion of any ingredient in their sunscreen products, 6.94% of the participants reported that they look for aloe, antioxidants, zinc, and zinc oxide when deciding to purchase their sunscreen products. The remaining 93.06% of the participants answered that they do not look for any particular desirable ingredient in their sunscreen products.

In the fourth section of the survey, the participants were asked to complete a reading regarding the advantages and risks of using sunscreen. Some of the questions in the first section of the survey were duplicated on purpose in order to evaluate any opinion change as a result of being informed of this controversy. In particular, questions 13, 14, 15, 17, 18, 23, 25, and 26 allowed for the choice of answering “I don’t know” in order to reduce uninformed or uneducated guesses from compromising the validity of the data. During the data analysis, any datum that selected the answer choice of “I don’t know” were omitted for that particular question.

To begin with, any opinion change regarding the perceived efficiency of sunscreen was evaluated via questions 8 and 20. The participants were asked to determine the efficiency of sunscreen on the scale of 1 to 5, where “1” showed the least efficient and “5” the most efficient.

The collected data indicates that while students initially rated the efficiency of sunscreen to be on average, 3.80, but after reading the educational excerpt, the average of the perceived efficiency decreased to 3.51. Using paired student's t-test, it was concluded that there was enough evidence to conclude that the true difference in means is not equal to zero ($p = 0.00665$) with 95% confidence. There is a significant decrease in the perceived efficiency of sunscreen when they are educated regarding the controversy surrounding sunscreen with a mean difference of 0.278.

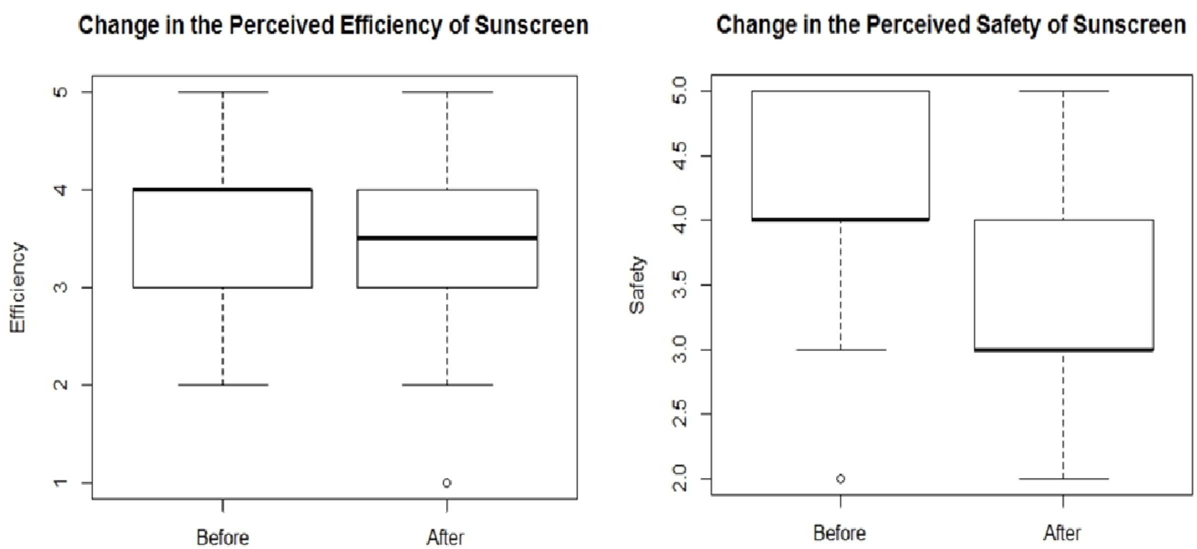

Figure 3: Change in the Perceived Efficiency of Sunscreen Use (left) and Change in the Perceived Safety of Sunscreen Use (right)

Any noticeable change in the perceived safety of the use of sunscreen was also determined by comparing student responses before and after the intervention. The participants were asked to determine the safety of sunscreen on the scale of 1 to 5, where "1" represented very dangerous and "5" very safe. The collected data indicates that while students gave an average of 4.18 rating on the how they perceived the safety of sunscreen to be, but it also decreased to an average of 3.32 after the intervention. Using paired student's t-test, there is enough evidence to conclude that the true difference in means is not equal to zero ($p = 4.27$) with 95% confidence. While there is a slight decrease in the perceived safety of sunscreen when they are educated regarding the controversy surrounding sunscreen, but the change is not statistically significant enough.

The perceived role of the use of sunscreen was determined by asking participants to rank the primary purposes of using sunscreen. The possible choices for reasons for using sunscreen included "reduce exposure to UV radiation," "reduce photoaging and wrinkle," "prevent sunburn," "prevent skin cancer," "prevent skin from tanning unintentionally," and "prevent skin from producing excessive amount of vitamin D." The majority of the participants ranked protection from UV exposure, prevention from skin cancer, prevention of sunburn, reduction of photoaging and wrinkles, prevention of the skin from tanning unintentionally, and prevention of the skin from producing excessive vitamin D to as the order of the perceived significance of the purposes of using sunscreen, respectively from the most significant to the least. The average ranking of the main purposes of sunscreen use did not change as a result of the introduction of the intervention. However, the distribution of responses changed slightly. For instance, more participants tended to select reduced exposure to UV radiation and skin cancer prevention more frequently after the introduction of the intervention.

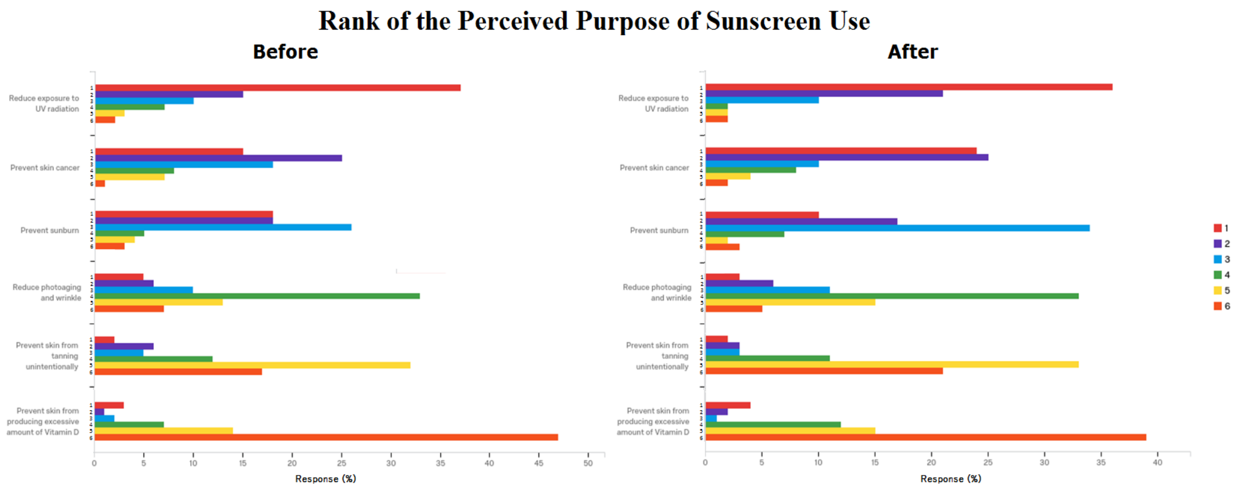

Figure 4: Ranking of the Primary Purposes of Sunscreen Use Before the Intervention (left) and After the Intervention (right). The reported ranking of each of the possible purposes are represented in percentages.

The excerpt did not change the participants' opinions significantly regarding protection from UV exposure can reduce the probability of obtaining skin cancer ($p = 0.402$). Both before and after reading the excerpt, the participants agreed that UV exposure is one of the primary reasons for developing skin cancer.

The participants were also asked to record the effect that skin cancer has on the physical comfort of the patient. They were asked to rank from 1 (not at all) to 5 (extremely). Prior to reading the excerpt, 73.61% of the participants identified that the degree of influence that skin cancer has on physical comfort is to be 5 or extreme, 11.11% answered 4, and 1.39% answered 1 or not at all. 13.89% of the participants answered that they do not know. After the intervention, 54.17% of the participants answered that the effect that skin cancer has on physical comfort is 5, 29.17% answered 4, and 12.5% answered 3. 4.17% of the students answered that they do not know. The excerpt seems to have educated and altered students' views regarding the correlation between skin cancer and physical comfort. The number of participants who could not answer due to a lack of knowledge on the topic decreased. A change in the distribution of the selected answer choice was detected as well, and the true difference in means decreased significantly (p-value = 0.00019) at 95% significance level.

The participants were prompted to predict their own chances of developing skin cancer in the next ten years, on a scale of 1 to 5, where 1 means not susceptible to skin cancer and 5 means very susceptible to the disease. Initially, the average susceptibility that the participants answered was 2.17. However, once students were educated regarding skin cancer in the excerpt, the perceived susceptibility to the disease increased to the average of 3.06. Based on the paired t-test, the true difference in means increased significantly (p =).

Finally, the participants were asked to answer questions regarding endocrine disruption and sunscreen as a potential endocrine disruptor. First, the participants were asked if they knew what endocrine disruption was. To this question, only about 26.39% of the participants answered "yes", and 73.61% of the participants answered "no." The majority of the participants (90.28%) were also not aware that many active ingredients in sunscreen are considered to be potential endocrine disruptors.

Then, the students were asked to evaluate the seriousness of endocrine disruption on a scale of 1 to 5, where 1 represents very dangerous and 5 represents very safe. When the participants were asked to rate the seriousness of endocrine disruptors, they answered with an average of 4.09. After the intervention, the perceived seriousness of endocrine disruptors shifted to an average to 3.78, indicating that after reading the excerpt, the participants perceived endocrine disruptors to be more dangerous. The change, however, is not statistically significant enough to conclude that the true difference in means is not equal ($p = 0.85$).

The participants were also prompted to determine the seriousness of Bisphenol A (BPA)—a commonly debated example of an endocrine disruptor. On a scale of 1 to 5, where 1 indicates very dangerous and 5 indicates very safe. Using a commonly known example of BPA, it was possible to confirm that the participants did consider endocrine disruptors such as BPA as serious health concerns.

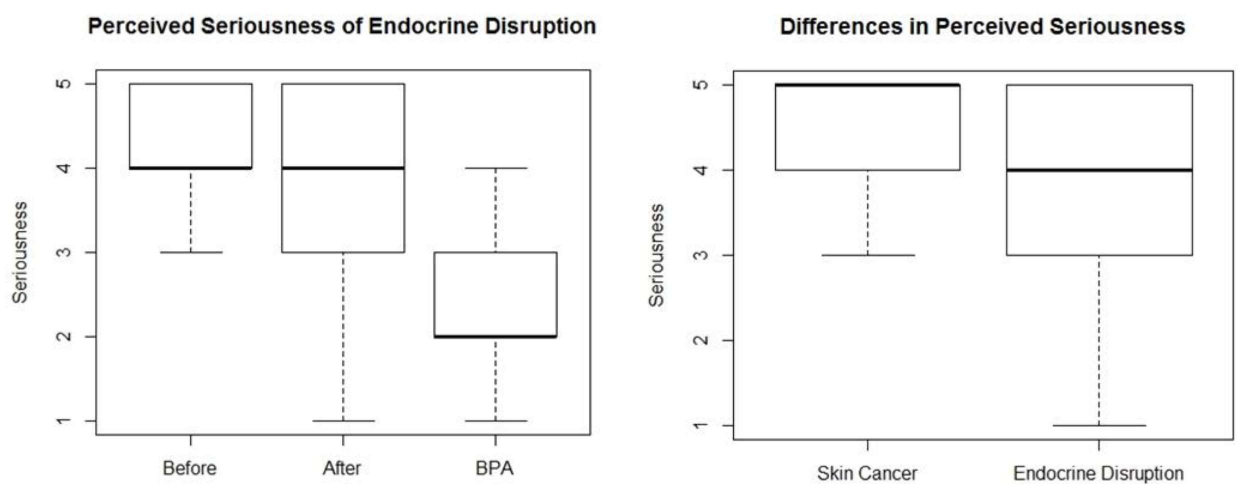

Figure 5: Change in the Perceived Seriousness of Endocrine Disruption due to Intervention (left), and the Comparison of the Seriousness of Skin Cancer versus Endocrine Disruption (right)

At the conclusion of the survey, the participants rated the seriousness of skin cancer versus endocrine disruption on a scale of 1 to 5, where 1 indicates “not serious” and 5 reflects “very serious.” The participants answered that skin cancer is much more serious, with an average of 4.09, than endocrine disruption, with an average of 2.41 ($p = 0.00124$). Furthermore, the median of the participants answered that they will “often” use sunscreen during summer months.

Discussion

Sun safety has been a significant health concern for our society, and there is a substantial need to address any potential issues or concerns in existing sun protection measures of sunscreen usage. It is difficult, however, to either fully acclaim or criticize sunscreen just based on evidences from previously-published scientific literature because evidences of the benefits and potential harm of sunscreen are both accumulating currently. As it is not possible to arbitrarily determine either skin disease or endocrine disruption to be a more severe issue at hand than another, a self-reported survey was performed in order to gather data on the opinions of undergraduate students at The University of Texas at Austin. The reported behavior and opinions of the participants provide another layer of consideration in determining a course of action to be recommended for sunscreen use in the future.

The survey questions were designed to enrich our understanding of the 1) sun safety behaviors of participants, 2) their knowledge regarding sunscreen, skin cancer, and endocrine disruption, and 3) any change in their opinion after reading a short educational excerpt regarding the benefits and potential harms of sunscreen use.

To begin with, a vast majority of the participants (84.72%) answered questions that pointed their estimated skin types to be skin types III, IV, and V according to the Fitzpatrick Skin Typing Test. These categorizations correspond to the descriptions of “sometimes burns,” “rarely burns,” and “never burns.” As students possess less photo-sensitive skin, the collected data may not be a generalized opinion shared by the general populous. Due to the small sample size, it was not possible to test for any trend in each skin type’s opinions regarding sunscreen and sun protection behaviors for further analysis.

According to the survey results, the participants of the survey spend a median of 1 to 2 hours outdoors during summer months, and the amount of time spent outside does not substantially increase over the weekend. While the majority of the students answered that they apply sunscreen when they plan to be outdoors, the short length of time that each student spends outdoors suggest that the students may not use sunscreen on a regular basis or reapply it every two hours during a normal day as recommended by the CDC (“Sun Safety”).

Possibly due to short exposure to the sun and less interest in sunscreen use in general, there seems to be a vast majority of the sampled participants that do not seem to read the sunscreen ingredient label (84.72%), do not purchase sunscreen with specific desirable ingredients (93.06%), and do not stay away from any particular ingredient (95.83%). The participants were asked to list any chemical that they could identify, and the list of chemical ingredients that the participants provided for the categories of desirable or undesirable reflected correct understanding of the effects that these ingredients have on skin health.

Next, participants' average level of sun exposure, opinions regarding sunscreen, and their knowledge on skin cancers and endocrine disruption were evaluated. Most importantly, this survey also provides glimpses on how young consumers make decisions when they are faced with the conflicting issues of sunscreen health benefits and harm. Therefore, some questions were provided in order to obtain information about the participants' prior knowledge regarding sunscreen chemicals were analyzed before the introduction of intervention—a short educational excerpt that explained both the arguments that support and criticize the use of sunscreen. Then, the identical set of questions were asked regarding the efficiency and safety of sunscreen, perceived danger of skin diseases and endocrine disruption after the intervention. The answers to these duplicated questions were compared in order to identify any shift in the participants' opinions regarding the use of sunscreen.

The analyzed data indicates that the perceived efficiency rating decreased significantly due to the introduction of the intervention. However, the perceived safety rating of sunscreen did not change significantly after the participants found out about the debate surrounding sunscreen use. Furthermore, the ranking order that the participants rated of the primary purpose of using sunscreen—in the order from highest to lowest, protection from UV exposure, prevention from skin cancer, prevention of sunburn, reduction of photoaging and wrinkles, prevention of the skin from tanning unintentionally, and prevention of the skin from producing excessive vitamin D—after the intervention even though there were slight variations in the distribution. These results reflect that further knowledge about sunscreen and details of the controversy caused the participants to feel less confident about both the efficiency and the safety of sunscreen, yet they still considered sunscreen to be quite safe. Furthermore, the results indicate that the participants acknowledge the importance of protection from UV exposure and skin cancer prevention—the top two ranked primary purposes of sunscreen—and consider sunscreen to be able to achieve these goals. It is quite interesting, however, that the students ranked the long-term goal of skin cancer prevention to be a more important primary purpose of sunscreen use than the short-term goal of sunburn prevention. Indeed, the participants responded that protection from UV exposure can reduce the probability of obtaining skin cancer, which was only confirmed after the intervention.

According to the survey data, skin cancer seems to be perceived as a much more serious form of disease than endocrine disruption. Upon reading the educational excerpt, the participants significantly altered their opinions to indicate that the effect that skin cancer has on the physical comfort of the patient is not as substantial. Even though the rate of skin cancer is the most prevalent form of cancer in the United States, most forms of skin cancer are highly curable, and this fact was provided in the educational excerpt. Based also on the fact that the majority of the participants do not have a family history of skin cancer (83.33%), the reduction in the participants' evaluation of skin cancer on health seems to acknowledge this fact from the educational excerpt. Despite this decrease, the average response of the perceived effect that sunscreen has on physical discomfort remains quite high, indicating that while the students consider skin cancer to be not as detrimental to health as they initially deemed, they still consider skin cancer to be an important health concern.

The participants were also asked questions to evaluate their knowledge on endocrine disruption and to measure any change in their opinion due to intervention. The survey data shows that most participants were not informed about endocrine disruption prior to the educational excerpt (73.61%). Even more participants were not aware of the argument that some sunscreen chemicals may be potential endocrine disruptors (90.28%).

A significantly larger number of participants answered that endocrine disruption is more dangerous after they had read the educational excerpt. However, when the seriousness that the participants perceive of skin cancer was compared to the seriousness of endocrine disruption, a significantly larger proportion of the participants answered that skin cancer is a more serious health issue than endocrine disruption. More than half of the participants also answered at the end of the survey that they plan on using sunscreen "often" during summer months.

In conclusion, when the public represented by the participants are provided with two conflicting evidences of the effect of sunscreen on human health, they prefer the continued use of sunscreen. The efficiency and safety ratings, as well as the comparison between the participants' response between endocrine disruption and skin cancer confirm that a significantly higher number of participants consider the prevention of UV overexposure and skin cancer to be a more important health issue compared to endocrine disruption.

Future Recommendations

The topic of sun safety and photoprotection are of increasing interest in the United States, with the rising number of skin diseases, such as skin cancer, that occur as a result of overexposure to UV rays. This case study serves as an important overview of the opinions of undergraduate students at The University of Texas at Austin. As the topic concerns an even wider age group, however, this case study can serve as a preliminary study for future follow-up studies with suggested improvements and modifications below.

First, due to the short duration of survey data collection, there were some limitations in this case study. It is important to determine how skin sensitivity affects awareness and decisions about sunscreen. Due to the small sample size, it was not possible to prove statistical significance that skin type has on the sun safety behaviors and the opinions that they may hold regarding the use of sunscreen. A larger pool sample size could be collected in order to test for the correlation.

Second, the data collected in this case study reflected the sun behavior and opinions only of undergraduate students at The University of Texas at Austin between the ages of 18 and 30. The specificity of the population was preferred for the purpose of this survey in order to identify the knowledge and opinions of undergraduate students. However, sunscreen use is not restricted only to this age and education group. For instance, if the sunscreens are proven to be endocrine disruptors and disrupt neurodevelopments, young children and mothers would be most affected by this discovery. Future follow-up studies can focus on collecting data from a more diverse groups of participants based on age, education level, and income status in order to reflect the opinions of a larger section of society.

Third, the survey could be modified to collect expert opinions from dermatologists and endocrinologists in the region in addition to collecting information from consumers. The ongoing debate and investigation regarding the potential dangers of sunscreen is not yet resolved. Therefore, consulting and analyzing the opinions of experts who may have experience with similar precedents could reveal a new layer of understanding to help provide answers to questions of whether sunscreen should continue to be used despite concerns raised about them as potential endocrine disruptors.

Expert opinions from primary care physicians and pro-sunscreen activists or critics could also enrich the overall understanding of the debate surrounding sunscreen. As both primary care physicians and activists work closely with the general population to prevent the occurrence of diseases such as skin cancer, these experts may relate another aspect in that sunscreen use is closely related to the health of the community, especially in economically or socially-marginalized populations that do not receive as many healthcare benefits.

Fourth, the survey could be more comprehensive for future studies. In order to minimize the length of the survey, many questions that pertain to the topic of sun safety and sunscreen use could not be asked in this survey. For instance, Fitzpatrick's scale consists of a series of questions that determine the overall sensitivity of skin to sun exposure. In this survey, however, the descriptions of each of Fitzpatrick's scale were directly asked to participants. Therefore, this survey would be less accurate in deducing the skin type of each participant, compared to asking participants the recommended series of questions to determine the skin type using Fitzpatrick's scale.

Fifth, UV exposure is a health concern not only during summer months and in the outdoor environment, but also throughout the year and indoors. For instance, according to the American Academy of Dermatology, sunscreen is also recommended to be used every day, all year around ("Sunscreen FAQs"). A follow-up study could evaluate the frequency of participants' use of sunscreen use during non-summer months, and if the use of sunscreen during those months led to a significant decrease in the instances of sunburn and other forms of skin diseases. Furthermore, the collected data indicates that very few participants apply sunscreen when they expect to be indoors only. The frequency of sunscreen use for those that spend most of their day indoors—such as students and office workers—and their opinions regarding sunscreen use and sun safety measures could contribute to a more holistic understanding of the public opinion.

Sixth, the correlation between SPF values and participants' sense of security can also be measured. Many dermatologists and experts have discussed the level of protection with increasing SPF value. The SPF value primarily measures the amount of protection from UV-B rays, and does not take UV-A rays into account. As both forms of UV radiations can cause skin diseases, SPF is not a reliable method of estimating overall UV protection. Furthermore, the level of UV-B protection does not increase as much as it is commonly thought of with increasing SPF values. For instance, when the UV-B protection increases the SPF value from 15 to 30, the percentage of UV protection only increases 4%, from 93% to 97%. These data may indicate that the frequency of sunscreen reapplication may result in a greater degree of protection than using sunscreens with higher SPF values. Likewise, the survey can be expanded in length in order to include more questions that improve the accuracy of the analysis.

Seventh, the data collection occurred in late November. Even though each question specifically asked participants' sun behaviors during summer months, the data may not be as accurate as it could have been if the survey data was collected during summer months. In order to ensure more accurate data collection of the participants' photoprotection behaviors and opinions regarding sunscreen, the same survey could be completed at different times of the year so that any change in the use or perception of sunscreen changes with seasonal and temperature changes.

Finally, a previous section of this thesis attempts to understand sun safety behaviors in another country—Australia—by comparing the federal policy in Australia with that in the United States. The regulations and public policies regarding sunscreen can provide an understanding of the legal processes that protect the health of its citizens as much as possible. Furthermore, medical data regarding the benefits of sunscreen on reducing incidences of various forms of skin cancer have been published in Australia. However, there is very limited existing literature that measures the perception and opinion changes that the participants undergo as a result of informing them further about both the positive and negative effects that sunscreen can have on human health. Therefore, collecting survey data from Australia and other nations that suffer from extraordinarily high incidences of skin cancer can provide an even more comprehensive understanding of the public's decision on debated commercial products with opposing bodies of scientific and medical evidences.

This case study provides a deeper understanding of the decisions that college students at The University of Texas at Austin may potentially make once they are aware of the debate surrounding sunscreen safety. Furthermore, it also serves as a preliminary study for future studies that attempt to evaluate sun safety behavior and opinions on skin cancer, endocrine disruption, and sunscreen use with the suggested improvements and modifications above.

Chapter 6: Discussion, Conclusion, and Suggestions

The purpose of this thesis was to evaluate the existing arguments surrounding sunscreen ingredients and to use a case study of sun behaviors and opinions of the undergraduate students at The University of Texas at Austin to make suggestions regarding methods for improving sun safety. In particular, the case study investigated any opinion changes regarding sunscreen use when they are educated with the debate.

First, previously-published literature was examined regarding the validity of endocrine disruption and skin cancer prevention. The evaluation of previous scientific evidences that either support or criticize sunscreen could not be compared meaningfully. The supporting evidences of sunscreen proved the benefits of sunscreen products, which is a combination of multiple sunscreen ingredients, including debated ones such as oxybenzone. On the other hand, the criticizing evidences of sunscreen focused on the effect that individual sunscreen chemicals may possess. As the two sides of the argument do not contend on the same level of specificity, it was not possible to derive a conclusion as to whether the evidences supporting sunscreen use was more substantial than the evidences against sunscreen use, or vice versa.

An argument suggested that the solution to the problem would be to give expedited approval of newer sunscreen chemicals that have been in use in Europe or in other countries so that the safer ingredients can be added to sunscreen. Australia was selected as a nation to compare with the United States because Australia experiences the highest rate of skin cancer incidences in the world. In Australia, sunscreen is considered as a drug as well, and Australia has an approved list of sunscreen ingredients that contains all of the approved level of the debated sunscreen chemical. Upon evaluation of the federal approval processes, it was confirmed that the current drug approval methods in the United States is possibly more extensive or complicated compared to that of Australia given that the United States has a substantially smaller list of approved sunscreen chemicals. This is disadvantageous because the United States currently has a much smaller list of approved sunscreen chemicals that give protection for UV-A radiation has been proven to contribute to skin diseases to a greater extent that it was previously thought of. The safety of each sunscreen chemical seems to be ensured as all of the sunscreen chemicals currently approved for use in the United States are used with either the same or higher maximum dosage in Australia.

Criticisms towards the slow FDA drug approval processes exist, but the comparison with the TGA indicates that the legal guidelines of both the United States and Australian governments endorse similar high standards of approval as they consider the classification of sunscreen more seriously. One way to improve the speed at which new sunscreen ingredients can be introduced to the market would be to endorse a new category of sunscreen that regulates it as a cosmetics rather than as a drug. Under this policy addition, it will be possible to continue maintain active sunscreen chemicals as both drugs and cosmetics, depending on the use and claims made by the product while continuing to regulate all sunscreen ingredients at different levels of surveillance.

In conclusion, the current scientific evidences and public policy measures seem to suggest that the use of the debated chemicals in commercial products is safe at the concentrations that are used today. While counterarguments against the safety of sunscreen chemicals as potential endocrine disruptors cannot be disregarded, the preventive effects of sunscreen in limiting incidences of skin cancers and skin diseases seem to outweigh the potential harm.

The survey of undergraduate students at The University of Texas at Austin suggests that the majority of the participants did not know the definition of endocrine disruption (73.61%) and also were not previously informed that some of the active ingredients in sunscreen are potential endocrine disruptors (90.28%). Once they were informed of the debate, the participants' score on the safety of sunscreen diminished. However, the participants still rated the seriousness of skin cancer to be statistically higher than that of endocrine disruption ($p = 0.0012$).

From the survey results, two conclusions can be made. First, a significantly higher number of people would choose skin cancer as a more dangerous form of disease than endocrine disruption. Given the high rate of skin cancer incidences today in the United States, such fear and concern about skin cancer seems to be quite justified.

Second, one possible reason that not many policy initiatives have been passed to improve the safety of sunscreen is possibly due to a lack of public knowledge on this debate. More accurately measuring public knowledge on sunscreen will require a future follow-up study that examines a larger sample of all age groups for their understanding and opinions regarding sunscreen given its role as endocrine disruptor. However, the survey results show that only 9.72% of the sample of undergraduate students age 18 and higher that are currently residing in Texas are informed of this debate.

One suggestion to reduce the concerns regarding the harm of sunscreen could be as simple as delivering the information surrounding sunscreen to the public. BPA is another potential endocrine disruptor, which unlike triclosan, continues to be used in multiple commercial products in the United States because the FDA has deemed it to be safe at the currently approved levels. However, due to many activist efforts to teach the public regarding the potential harmful effects of BPA, an increasing number of companies, especially those that produce commodities that come in contact with children and pregnant women, are voluntarily choosing to not include BPA in their production as a positive branding effort. As the health-related debates surrounding BPA are similar to those surrounding sunscreen ingredients, educational efforts can result in the production of safer sunscreen products.

When the participants of the self-reported survey were asked to rank the primary purpose of using sunscreen, they agreed that the most important purpose is protection from UV radiations. Then, they ranked the long-term goal of skin cancer prevention to be a more important purpose of sunscreen use than the short-term goal of sunburn prevention. This implies that the population represented by the sample data consider sunscreen as a commercial product that they will encounter frequently for a long period of time. Therefore, while prevailing data suggest the continued use of existing sunscreen products to achieve protection from skin cancer,

This thesis investigated the role, safety, and effectiveness of sunscreen using previously-published scientific data, list of approved sunscreen chemicals in both the United States and in Australia, and self-reported survey results. Given the bodies of evidences that surround the health benefits and concern of sunscreen chemicals, it was concluded that sunscreen should continue to be used given its clear benefits in preventing skin diseases. However, the FDA policy in regulating sunscreen should be extended to make a larger variety of sunscreen chemicals available to the market for better photoprotection and the awareness of endocrine disruptors in commercial products should be raised. These conclusions and recommendations suggest possible ways of more safely using sunscreen by understanding the health issues that surround it. Future follow-up research can further enhance and confirm the safety and effectiveness of the existing sun protection behaviors.

Appendix

Appendix A: Self-Reported Survey Questionnaire

I. General Information

1. Gender

    a. Male

    b. Female

2. After spending all day under the sun, how does your skin naturally react?

    a. Always burns, blisters and peels

    b. Often burns, blisters and peels

    c. Sometimes burns

    d. Rarely burns

    e. Never burns

3. How many freckles or moles do you have on unexposed areas of your skin?

    a. Many (25+)

    b. Several (10-20)

    c. A few (5-10)

    d. Very few (1-5)

    e. None

II. Sun Behavior

4. On a typical summer day (June to August), how many hours do you spend outdoors between 10 a.m. and 5 p.m. on **weekdays** (Monday-Friday)?

a. less than 1 hour

b. 1 – 2 hours

c. 3 – 4 hours

d. 5 - 6 hours

e. 7+ hours

5. On a typical summer day, how many hours do you spend outdoors between 10 a.m. and 5 p.m. on **weekends** (Saturday-Sunday)?

a. less than 1 hour

b. 1 – 2 hours

c. 3 – 4 hours

d. 5 - 6 hours

e. 7+ hours

6. Do you apply sunscreen only if you expect to be outdoors?

a. Yes (Only when I expect to be outdoors)

b. No (I also apply sunscreen when I am indoors)

c. Sometimes

7. What do you perceive to be the **primary role of sunscreen**? (Please Rank)

a. Reduce exposure to UV radiation ____

b. Reduce photoaging and wrinkles ____

c. Prevent sunburn ____

d. Prevent skin cancer ____

e. Prevent skin from tanning unintentionally ____

f. Prevent skin from producing excessive amount of Vitamin D ___

8. How efficient do you think sunscreen are? (1 – Least efficient, 5 – Most efficient)

0 1 2 3 4 5

9. How safe do you think sunscreen are? (1 – Dangerous, 5 – Safe)

0 1 2 3 4 5

10. Have you read the ingredient label on sunscreen products? If yes, please list.

a. Yes ( )

b. No

11. Is there any chemical ingredient in sunscreen that you stay away from?

a. Yes ( )

b. No

12. Is there any chemical ingredient in sunscreen that you want in your product?

a. Yes ( )

b. No

13. How severely would developing skin cancers disrupt your personal health and physical comfort? (1 – Not at all, 5 – Extremely)

0 1 2 3 4 5 I do not know

14. How would you rate your chances of developing skin cancer in the next 10 years? (1 – Not at all susceptible, 5 – Very susceptible)

0 1 2 3 4 5 I do not know

15. If people protected themselves from the sun, would they not be as likely to get skin cancer? (1 – Strongly disagree, 5 – Strongly agree)

0 1 2 3 4 5 I do not know

16. Do you know what “endocrine disruptors” are?

a. Yes

b. No

17. How serious do you think endocrine disruption is? (1 – Not serious, 5 – Serious)

0 1 2 3 4 5 I do not know

18. What are your feelings about BPA? (1 – Dangerous, 5 – Safe)

0 1 2 3 4 5 I do not know

III. Reading

Please answer the following questions after reading the information below.

In the past decade, there has been an ongoing debate regarding the safety of sunscreen. While many researchers continued to find the efficacy of sunscreen in preventing sunburns and most forms of skin cancers—including melanoma—some researchers are arguing that some of the most common sunscreen chemicals are endocrine disruptors.

a) Pros of Using Sunscreen

a. Exposure to UV radiation of the sun causes skin cancer. Sunscreen prevents UV exposure on the skin and is the most effective prevention measure for most skin diseases, including sunburn and skin cancers.

b. Skin cancer is the most common form of cancer in the U.S. One in five people experience a skin cancer in the U.S [8, 9].

c. Melanoma is one of the most common cancers for adolescents and young adults between 15 - 29 years of age [11].

d. Research shows that skin pigmentation does not reduce the risk of skin cancer: while population of lighter skin show higher skin cancer incidences, population of color show higher morbidity and mortality [1].

e. Sunburn early in life is a risk factor for skin cancer.

f. Most skin cancers are not fatal and are treatable if detected early.

b) Cons of Using Sunscreen

a. Many active ingredients used in most store bought sunscreen in the U.S. are *potential* endocrine disruptors chemicals that may interfere with the body's endocrine system.

b. Increased amount of research results show that endocrine disruptors can affect hormone balance in both adults and children.

i. In adults, endocrine disruptors show adverse effects on human reproductive, nervous, and immune systems.

ii. In children, endocrine disruptors can have significant consequences on bothmental and physical developments in children.

c. Even though most forms of sunscreen are topically applied, many of theendocrine disrupting sunscreen chemicals have been found in breast milk and urinesamples at high concentrations [5].

d. However, according to the American Academy of Dermatology, “No published studies show that sunscreen is toxic to humans or hazardous to human health” [4].

III. Reading Responses

Please answer the following questions. Some questions are repeated on purpose. Please take a moment to see if the article revised your opinion.

19. Did you know that many active ingredients in sunscreen are “endocrine disruptors,” prior to reading this article?

a. Yes

b. No

20. How efficient do you think sunscreen are? (1 – Least efficient, 5 – Most efficient)

0 1 2 3 4 5

21. How safe do you think sunscreen are? (1 – Dangerous, 5 – Safe)

0 1 2 3 4 5

22. In your opinion, how susceptible are you to developing skin cancer in the next 10 years? (1 – Not at all susceptible, 5 – Very susceptible)

0 1 2 3 4 5 I do not know

23. How serious do you think skin cancers are? (1 – Not serious, 5 – Serious)

0 1 2 3 4 5 I do not know

24. Do you or any members of your family have a skin cancer history?

a. Yes

b. No

25. If people protected themselves from the sun, would they not be as likely to get skin cancer? (1 – Strongly disagree, 5 – Strongly agree)

0 1 2 3 4 5 I do not know

26. How serious do you think endocrine disruption is? (1 – Not serious, 5 – Serious)

0 1 2 3 4 5 I do not know

27. How often do you plan on using sunscreen during summer months (June to August)?

a. No, I will not use sunscreen

b. Rarely

c. Sometimes

d. Often

e. Always

28. What do you perceive to be the primary role of sunscreen? (Please Rank)

a. Reduce exposure to UV radiation ____

b. Reduce photoaging and wrinkle ____

c. Prevent sunburn ____

d. Prevent skin cancer ____

e. Prevent skin from tanning unintentionally ____

f. Prevent skin from producing excessive amount of Vitamin D ___

Appendix B: IRB Approval Document

OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

P.O. Box 7426, Austin, Texas 78713 · Mail Code A3200
(512) 471-8871 · FAX (512) 471-8873

FWA # 00002030

Date: 11/22/16

PI: Gwendolyn M Stovall

Dept: Plan II Honors Program

Title: The Evaluation of Sunscreen Ingredients, Safety, and Policies in the United States

Re: IRB Expedited Approval for Protocol Number 2016-09-0063

Dear Gwendolyn M Stovall:

In accordance with the Federal Regulations the Institutional Review Board (IRB) reviewed the above referenced research study and found it met the requirements for approval under the Expedited category noted below for the following period of time: 11/22/2016 to 11/21/2017. *Expires 12 a.m. [midnight] of this date.* If the research will be conducted at more than one site, you may initiate research at any site from which you have a letter granting you permission to conduct the research. You should retain a copy of the letter in your files.

Expedited category of approval:

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ 3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples:
(a) Hair and nail clippings in a non-disfiguring manner.
(b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
(c) Permanent teeth if routine patient care indicates a need for extraction.

(d) Excreta and external secretions (including sweat).
(e) Uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue.
(f) Placenta removed at delivery.
(g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
(j) Sputum collected after saline mist nebulization.

☐ 4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
Examples:
(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
(b) Weighing or testing sensory acuity.
(c) Magnetic resonance imaging.
(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

☒ Use the attached approved informed consent document(s).

☒ You have been granted a Waiver of Documentation of Consent according to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1).

☐ You have been granted a Waiver of Informed Consent according to 45 CFR 46.116(d).

Responsibilities of the Principal Investigator:

1. Report immediately to the IRB any unanticipated problems.

2. Submit for review and approval by the IRB all modifications to the protocol or consent form(s). Ensure the proposed changes in the approved research are not applied without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Changes in approved research implemented without IRB review and approval initiated to eliminate apparent immediate hazards to the subject must be promptly reported to the IRB, and will be reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the subjects continued welfare.

3. Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to participate.

4. Ensure that only persons formally approved by the IRB enroll subjects.

5. Use only a currently approved consent form, if applicable.
   Note: Approval periods are for 12 months or less.

6. Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of subjects and their information.

7. Submit a Continuing Review Application for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year a reminder letter will be sent to you two months before your expiration date. If a reminder is not received from Office of Research Support (ORS) about your upcoming continuing review, it is still the primary responsibility of the Principal Investigator not to conduct research activities on or after the expiration date. The Continuing Review Application must be submitted, reviewed and approved, before the expiration date.

8. Upon completion of the research study, a Closure Report must be submitted to the ORS.

9. Include the IRB study number on all future correspondence relating to this protocol.

If you have any questions contact the ORS by phone at (512) 471-8871 or via e-mail at orsc@uts.cc.utexas.edu.

Sincerely,

James P. Wilson

James Wilson, Ph.D.
Institutional Review Board Chair

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Biography

Hyun J. Jung, or Helen, was born in Seoul, Korea on April 8, 1993, and she moved with her family to Austin, Texas in 2005. She enrolled in Plan II Honors program and Biochemistry at The University of Texas at Austin in 2012 and studied about rainforest conservation in her junior year in Costa Rica. In college, she was an active member of the American Red Cross and edited the university's interdisciplinary research journal named the Undergraduate Research Journal. She plans on applying to medical schools after graduating in the Fall 2016.